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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,324	12/01/2003	Jong Wook Son	A36093 073226.0121	2695

38485 7590 07/18/2005

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EXAMINER	
TATE, CHRISTOPHER ROBIN	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 07/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/725,324	SON ET AL.	
	Examiner	Art Unit	
	Christopher R. Tate	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5 and 6* is/are rejected.

7)☒ Claim(s) *1,2,5 and 6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1203*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-8 are presented for examination on the merits.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 5 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kweon et al (KR 2003-0056753 - English Abstract provided in IDS submitted 12/01/2003).

The claims are drawn to a composition comprising water-soluble chitosan (within a particular molecular weight range) and an *Hibiscus* extract as well as a method of inducing weight reduction via administering the composition to a subject.

The cited reference teaches an edible weight-loss composition which appears to be identical to the presently claimed composition since the reference composition also contains water-soluble chitosan and an *Hibiscus* extract therein. Consequently, the claimed composition appears to be anticipated by the reference (as does the inevitable oral administration of the reference composition to such a subject).

In the alternative, even if the claimed composition is not identical to the referenced composition with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced composition is likely to inherently possess the same characteristics of the claimed composition particularly in view of the similar characteristics which they have been shown to share - e.g., with respect to their ability to induce/control weight-loss. Thus, the claimed composition would have been obvious to those of ordinary skill in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

With respect to the above art rejection, please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' water-soluble chitosan differs and, if so, to what extent, from the water-soluble chitosan within the composition disclosed by the cited reference (e.g., with respect to the molecular weight thereof). Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Claim Rejections - 35 USC § 103

Claims 1, 2, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kweon et al. (KR 2003-0056753 - English Abstract provided in IDS submitted 12/01/2003) in view of Tanzawa et al. (JP 62184002 - CAPLUS and JPAB English Abstracts) and Grace (US 6,426,077).

Kweon et al. teach an edible weight-loss composition comprising water-soluble chitosan and an *Hibiscus* extract therein. Kweon et al. do not appear to expressly teach using the particular low molecular weight water-soluble chitosan instantly claimed, nor the inclusion of L-carnitine within such a weight-loss composition.

Tanzawa et al. beneficially teach a low molecular weight water-soluble chitosan (having a molecular weight of approximately 2800) which is easily useful within therapeutic (drug) preparations (see CAPLUS and JPAB Abstracts). Grace et al. teach a weight-loss composition which beneficially comprises L-carnitine (as well as chitosan) as an effective fat-burner therein (see, e.g.. col 1, lines 6-9; col 2, lines 39-44; claims 6, 8, and 25).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize an easy-to-employ low molecular weight (i.e., within the instantly claimed MW range) water-soluble chitosan within the therapeutic weight-loss composition taught by Kweon based upon the beneficial teachings provided by Tanzawa et al., as discussed above. With respect to combining a water-soluble chitosan, an *Hibiscus* extract, and L-carnitine, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine such ingredients for their known benefit since each is well known in the art for the same purpose (i.e., for promoting weight loss in a subject) and for the following reasons. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, In re Sussman, 1943 C.D. 518; In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279

F.2d 274, 276-277; 126 USPQ 186, 188 (1960). Applicants invention is predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients (such as the % wt amounts/ratios recited in instant claims 3, 4, 7, and 8 - which the instant specification reasonably discloses provides such synergism). Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *ipso facto* unpatentable.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above-cited references before him/her.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 1, 2, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (KR 200110103065 - Full English translation enclosed), in view of Tanzawa et al. (JP 62184002 - CAPLUS and JPAB English Abstracts).

Lee et al. (KR 200110103065) teach a composition for weight reduction (weight loss) which comprises *Hibiscus* extract as an active weight-loss ingredient therein. In addition, Lee et

al. disclose that the weight-reduction may also beneficially comprise chitosan and/or L-carnitine as active weight-loss ingredients therein (see entire document including pages 2, 4, 5, 9, 10; and claims). Lee et al. do not expressly teach the use of a water-soluble chitosan having a molecular weight within the claimed range.

Tanzawa et al. beneficially teach a low molecular weight water-soluble chitosan (having a molecular weight of approximately 2800) which is easily useful within therapeutic (drug) preparations (see CAPLUS and JPAB Abstracts).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize an easy-to-employ low molecular weight (i.e., within the instantly claimed MW range) water-soluble chitosan within the therapeutic weight-loss composition taught by Lee et al. based upon the beneficial teachings provided by Tanzawa et al., as discussed above. With respect to combining such a water-soluble chitosan, an *Hibiscus* extract, and L-carnitine, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine such ingredients for their known benefit since each is well known in the art for the same purpose (i.e., for promoting weight loss in a subject) and for the following reasons. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, In re Sussman, 1943 C.D. 518; In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Applicants invention is predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon highly dependent upon specific proportions and/or amounts of particular ingredients (such as the % wt amounts/ratios recited in instant claims 3, 4, 7, and 8 - which the instant specification reasonably discloses provides such synergism). Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *ipso facto* unpatentable.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above-cited references before him/her.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claim Objections

Claims 3, 4, 7, and 8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record does not teach or reasonably suggest a weight-loss composition comprising the claimed ingredients within the % wt amounts/ratios recited in claims 3, 4, 7, and 8 (or method of inducing weight therewith) - given that the recited % wt amounts/ratios therein are reasonably disclosed within the instant specification as providing unexpected synergism to such a weight-loss composition.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher R. Tate
Primary Examiner
Art Unit 1655